Conversion to Universal Plasma

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The official link for this solicitation is:
http://www.acq.osd.mil/osbp/sbir/solicitations/sttr2015B/index.shtml

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Description:

Demand for plasma-based therapies continues to rise. In the US alone, there were ~29 million donations of plasma in 20131. Plasma-based therapies are also in high demand in the military. Warfighters with combat casualties often require massive plasma transfusions for trauma, shock, burn injury, and emergency surgery. Today, only Type AB blood donors, who account for only 4% of the overall donor population, are considered universal plasma donors. This greatly limits the overall plasma donor pool, and necessitates time-consuming and costly screening of non-AB plasma. The restricted donor pool poses additional logistic challenges to already complicated blood transfusion practices in the far-forward setting.2 Anti-A and anti-B (IgG and IgM antibodies) found in plasma from Type A, B or O donors can mediate blood cell hemolysis if not appropriately matched. These antibodies bind to A and B blood group antigens found on the surfaces of red blood cells, lymphocytes, endothelial cells and platelets in a recipient, triggering potentially dangerous hemolytic transfusion reactions. Plasma from Type AB blood donors lack these antibodies and do not cause hemolytic reactions. Therefore, blood purification/extraction technologies that selectively remove anti-A and anti-B antibodies from plasma can potentially produce universal plasma and significantly expand the plasma donor pool. One potential solution is the passage of plasma through a small, portable, biocompatible filter that can efficiently and selectively remove anti-A and anti-B (IgG and IgM antibodies) from plasma while sparing beneficial substances in plasma such as coagulation factors and albumin. Such a filter should ideally be: • Easy to implement with little to no supervision • Capable of being used at the point of plasma collection or transfusion, using gravity alone with no

change in standard transfusion times • Easily stored at ambient temperature without the need of refrigeration, with a shelf-life of more than 2 years • Devoid of biologics, antibodies or ligands that can leach or degrade over time • Simple to manufacture and gamma sterilizable • Easy to use and not cost prohibitive. PHASE I: The contractor will develop and screen various chemical / synthetic modifications of the base filtration technology, optimizing anti-A and anti-B antibody removal capacity as a proof-of-concept. As the feasibility criteria for Phase I, the contractor is required to demonstrate at least 70% selective removal of anti-A and/or anti-B (IgG and IgM antibodies) from plasma, while avoiding the removal of no more than 25% of coagulation factors and beneficial substances. Beneficial substances include albumin, total IgG, certain coagulation factors, and electrolytes (Na+, K+, and Ca2+). The research plan should include a R&D concept and in vitro screening methods to support the investigation. PHASE II: The contractor will down select the optimal filtration technology developed in Phase I and target anti-A and anti-B (IgG and IgM antibodies) removal of >90%, while removing no more than 10% of coagulation factors and beneficial substances. The Phase II research plan should incorporate a detailed product design specification and plan for custom tooling, manufacturing, and final delivery of a prototype DHP - 7 filtration/extraction device. The contractor shall furthermore demonstrate device compatibility with gamma sterilization. PHASE III: The contractor will conduct an animal safety and efficacy study. The device should be tested for ISO 10993 biocompatibility and immunohematological compatibility testing and be compatible with standard hospital transfusion and blood filtration equipment. The contractor will be required to apply for IDE approval from the FDA to run a small human pilot trial. This device could expand the plasma donor pool and alleviate substantial donor transfusion restrictions in definitive care, combat casualty care, and austere environments globally.